3M General Offices

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3M

Certified Mail

June 28, 2004

Document Processing Center
EPA East – Room 6428 Attn: Section 8(e)
Office of Pollution Prevention and Toxics
US EPA
1200 Pennsylvania Avenue NW
Washington DC 20460-0001

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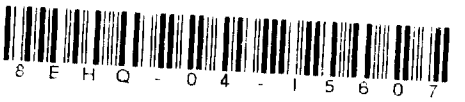

RE: TSCA 8(E) SUBSTANTIAL RISK NOTICE ON:
protective material

Dear Sirs:

3M has received preliminary results for a four-hour acute inhalation study in rats conducted with a protective material. The composition for this test substance is attached.

The study was conducted by TNO Nutrition and Food Research. Eight male and eight female rats were exposed to the test substance vapor at 5.4 mg/L for four hours. Animals were scheduled to be observed for fourteen days.

Shortly after exposure, all animals showed slight breathing abnormalities, slight or moderate sluggishness, piloerection, and blepharospasm. Within one day of exposure, all animals were observed to have labored breathing and body weight loss. Within four days of exposure, two male and two female rats had died.

The test material is an industrial (non-consumer) product commercially available in Europe. Trained operators apply the product using low-pressure spray equipment, which forms large (40-200 microns), non-respirable droplets compared to the aerosolized particles (1-2 microns) used in the subject study. 3M has conducted an exposure assessment which indicates minimal-to-no respirable exposure to this product when used as directed.

Two earlier studies are relevant to EPA's analysis of these results. First, 3M had previously conducted an acute inhalation study on a solvent control (the test substance with all components except the active ingredient) at 5.5 mg/L. In this study, two male and two female rats showed slight breathing abnormalities during exposure, but these effects were no longer observed shortly after exposure.

Second, 3M had previously conducted an acute inhalation study on a related product (containing 1.2% active ingredient) at 20.7 mg/L. One of the eight animals exposed

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(four of each sex), scheduled for sacrifice immediately after exposure, died before necropsy. Seven of the remaining eight animals (four of each sex) died during the scheduled fourteen-day observation period, and the final animal was sacrificed due to its moribund condition. This study had not been reported earlier because there was no exposure as the formulation was never commercialized, and the results of the study could not definitively be attributed to the active ingredient. We have included it as supplemental information in this submittal. Enclosed please find "Augmented acute (4-hour) inhalation toxicity study with T-7875 in rats."

A final report will be forwarded to EPA when received.

Once a docket number has been assigned for this submittal, please send the docket number postal card to Cheri Kedrowski, 3M Center Bldg. 220-2E-02, St. Paul, MN 55144.

Please contact Roger Perkins, Ph.D., DABT (651-733-3222) if you have any questions or if we can provide additional information.

Confidentiality claim:
The specific chemical identity of one ingredient of the test substance is held to be confidential business information until a patent application is filed.

Sincerely,

Larry R. Zobel, MD MPH
Staff Vice President and Medical Director

Protective Material
Test Substance Composition

Chemical Name	CAS #	Concentration (%)
Lemon Fragrance (AR111968 from CPL Aromas)	None	0.02
Ethyl Acetate	141-78-6	0.7
Methoxymethylethoxypropanol	34590-94-8	19.4
C9-C12-iso-alkanes	90622-57-4	77.88
[Copolymer of perfluoroalkylsulfonamidoalkyl acrylate and alkyl acrylate modified fatty acid dimmers]	None	2.0